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| APPLICATION NO.                                     | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/597,851  | 08/09/2006  | Karlheinz Bortlik    | 112701-746          | 7063             |
| 29157   | 7590        | 05/28/2009           | EXAMINER            |                  |
| K&L Gates LLP<br>P.O. Box 1135<br>CHICAGO, IL 60690 |             |                      | CHEN, CATHERYNE     |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1655                |                  |
|   |             |                      | NOTIFICATION DATE   | DELIVERY MODE    |
|   |             |                      | 05/28/2009          | ELECTRONIC       |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/597,851 | <b>Applicant(s)</b><br>BORTLIK ET AL. |  |
|                              | <b>Examiner</b><br>CATHERYNE CHEN    | <b>Art Unit</b><br>1655               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 8, 9, 11-23 and 25 is/are pending in the application.
- 4a) Of the above claim(s) 17-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8-9, 11-16, 22-23, 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The Amendments filed on Feb. 9, 2009 has been received and entered.

Claims 1-4, 8-9, 11-16, 22-23, and 25 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 8-9, 11-12, 15, 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Clinton et al. (1996, Cancer Epidemiology, Biomarker & Prevention, 5:823-833).

Clinton et al. teaches all trans lycopene accounts for 79-91% and cis lycopene isomers for 9-21% of total lycopene in tomatoes, tomato paste, and tomato soup (Abstract, right column). Thus, cis:trans at 20:80 is anticipated. The limitation enriched is taught because tomato paste is extracted and concentrated tomato. Tomato soup inherently has salt as flavorant; thus, the limitation of Claim 12 is taught.

Clinton et al. does not specifically teach using lycopene to improve skin health. However, the method of improving skin health is considered to inherently teach the claimed method because both the reference and the claimed invention are administering the same composition to the same patient. The patient is the same because every person has skin. Thus, on the administration of lycopene to any patient, an improvement of skin health would have had to occur if applicant's invention function as claimed.

***Claim Rejections - 35 USC § 103***

Claims 1-4, 8-9, 12-16, 22-23, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartal et al. (US 5965183) and Chandler et al. (1987, J. Food Sci., 52, 669-672) for the reasons set forth in the previous Office Action, which are set forth below. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive.

Hartal et al. teaches lycopene concentrates for use in food coloring, nutraceuticals, pharmaceuticals, and cosmetic formulations, lycopene from vegetable extracts (column 1, lines 7-9, 16-19), food-compatible liquid, pharmaceutically-acceptable liquid, cosmetically-acceptable liquid (column 6, lines 26-42), oleoresin contains about 2-10% lycopene (Claim 17). Lycopene occurs naturally in tomatoes (column 1, lines 17-18). Thus at least one carotenoid compound is taught by the reference.

However, it does not teach 20:80 cis-trans and the specific carotenoid compounds, improving skin.

Art Unit: 1655

Chandler et al. teaches provitamin A carotenoids are plentiful in human foods (Introduction, first paragraph). Cis-trans beta carotene isomers found in fruits and vegetable are 15.7% cis and 75.4% trans in sweet potato; 10.1% cis and 72.8% trans in carrot; 8.8% cis and 80% trans spinach; 16.6% cis and 71.8% trans in collard green; 13.5% cis and 76.7 trans nectarine; 15.4% cis and 76.7% trans in plum (Table 2, page 671).

The method of improving skin is considered to intrinsically teach the claimed method because both the references and the claimed invention are administering the same composition to the same patient. The patient is the same because every person has skin. Thus, on the administration of carotenoids to any patient, an improvement of skin would have had to occur if applicant's invention function as claimed.

Chandler et al. teaches provitamin A carotenoids are plentiful in human foods (Introduction, first paragraph). Hartal et al. teaches lycopene concentrates for use in food coloring, nutraceuticals, pharmaceuticals, and cosmetic formulations, lycopene from vegetable extracts (column 1, lines 7-9, 16-19). Lycopene is a type of carotenoids. Thus, an artisan of ordinary skill would reasonably expect that lycopene could be used as the types carotenoid taught by the references. This reasonable expectation of success would motivate the artisan to use lycopene in the reference composition. Thus, using lycopene is considered an obvious modification of the references.

The references do not specifically teach adding the ingredients in the amounts claimed by applicant for oral consumption. However, the reference

Art Unit: 1655

does teach the composition in food and cis-trans beta carotene isomers are found in fruits and vegetable with 15.7% cis and 75.4% trans in sweet potato; 10.1% cis and 72.8% trans in carrot; 8.8% cis and 80% trans spinach; 16.6% cis and 71.8% trans in collard green; 13.5% cis and 76.7 trans nectarine; 15.4% cis and 76.7% trans in plum (Table 2, page 671). The amount of a specific ingredient in a composition that is used for a particular purpose (the composition itself or that particular ingredient) is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Applicant's arguments concerning the USC 103 rejection above have been carefully considered but are not deemed persuasive of error in the rejection.

Applicant argues that 20:80 cis:trans isomer ratio of carotenoid compound is not taught.

Art Unit: 1655

In response to Applicant's argument, Hartal et al. teaches lycopene concentrates for use in food coloring, nutraceuticals, pharmaceuticals, and cosmetic formulations, lycopene from vegetable extracts (column 1, lines 7-9, 16-19), food-compatible liquid, pharmaceutically-acceptable liquid, cosmetically-acceptable liquid (column 6, lines 26-42), oleoresin contains about 2-10% lycopene (Claim 17). Lycopene occurs naturally in tomatoes (column 1, lines 17-18). Lycopene contains cis:trans isomers at the claimed range from 20:80 cis:trans ratio. Clinton et al. shows all trans lycopene accounts for 70-91% and cis lycopene isomers for 9-21% of the total lycopene in tomatoes, tomato paste, and tomato soup (see right column of Abstract, Clinton et al., 1996, 5: 823-833), which is within 20:80 cis:trans isomer ranges. Thus, the claimed range of cis:trans isomer in lycopene is taught.

Applicant argues that Chandler teaches away from the claims.

In response to Applicant's argument, Chandler is used to teach food with different ranges of cis:trans isomers. Chandler recognizes that isomerization of all trans to cis isomers reduces bioavailability; thus, one would not want to change all trans to cis isoforms for the food. As Applicant has claimed 20:80 cis:trans isomers, not all the isoforms are trans or cis. Thus, Chandler does not teach away from the invention.

### ***Conclusion***

No Claim is allowed.

Art Unit: 1655

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERYNE CHEN whose telephone number is (571)272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

cc

/Christopher R. Tate/  
Primary Examiner, Art Unit 1655